JUN 2 5 2001

Dräger

K003068

Datei: Summary.RTF
Date: Sep 18, 2000
Author: Frank Clanzett

510(k) SUMMARY
Summary of Safety and Effectiveness

APPLICANTS NAME AND ADDRESS:
Frank Clanzett
Regulatory Affairs
Dräger Medizintechnik GmbH,
Moislinger Allee 53-55
23542 Lübeck / Germany

APPLICANTS TELEPHONE NUMBER:
(01149)-451-882-3915

APPLICANTS FACSIMILE NUMBER:
(01149)-451-882-3915

APPLICANTS CONTACT PERSON IN THE USA:
Jim Brennan
Director Regulatory Affairs, Dräger Medical, Inc.
3135 Quarry Road
Telford, PA 18969
phone: 215-721-5400
fax: 215-723-5934

DATE THE SUMMARY WAS PREPARED:
September 18, 2000

DEVICE NAME:

Trade Name:	Savina
Common Name:	Intensive Care Ventilator
Classification Name:	Ventilator, Continuous

LEGALLY MARKETED DEVICE TO WHICH DRÄGER IS CLAIMING SUBSTANTIAL EQUIVALENCE:

Evita 2 dura - Manufactured by Dräger Medizintechnik, Lübeck, Germany and sold in the United States by Dräger Medical, Inc.

T-Bird ASV- Manufactured by Bird, USA

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DESCRIPTION OF THE DEVICE:

The Savina is an microprocessor controlled intensive care ventilator.

Savina generates the compressed air for ventilation with a blower, which means Savina is able to ventilate without connection of air or oxygen.

A controllable valve is switched in parallel with the blower to regulate the pre-set ventilation parameters. The valve opens or closes according to the ventilation parameter set.

INTENDED USE OF THE DEVICE SAVINA

Long term ventilator for intensive care.
For patient requiring tidal volume starting at 50 ml.

The indented areas for use are:
In the Intensive Care ward or in the recovery room.
During secondary transfer from one hospital to another.
During transfer of ventilated patients within the hospital.

The device applies the following ventilation modes:

CMV	Continuous Mandatory Ventilation
CMV_{Assist}	Assisted ventilation with continuous positive airway pressure.
SIMV	Synchronised Intermittent Mandatory Ventilation
CPAP	Continuous Positive Airway Pressure
PSV	Pressure Support Ventilation
BIPAP (PCV+)	Biphasic Positive Airway Pressure

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SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES:

The Savina ventilator is substantially equivalent to the predicate devices Evita 2 dura from Dräger and the T-Bird ASV from Bird.

All features of the Savina are also covered by the predicate devices the devices have nearly the same intended use. The performance characteristics from the Savina are similar to those of the predicate devices.
Technical mechanism of the turbine is also used in the T-Bird ventilator.

The Savina fulfils at least the same international standards as the predicate device Evita 2 dura of Dräger and has been tested according to these standards.

Therefore the Savina is as safe and effective as the predicate devices.

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Frank Clanzett
Regulatory Affairs
Dräger Medizintechnik GmbH, Germany

Sep. 18, 2000

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 5 2001

Mr. James J. Brennan
Dräger Medizintechnik GmbH
c/o Dräger Medical, Inc.
3135 Quarry Road
Telford, PA 18969

Re: K003068
Savina Intensive Care Ventilator
Regulation Number: 868.5895
Regulatory Class: II (two)
Product Code: CBK
Dated: June 15, 2001
Received: June 18, 2001

Dear Mr. Brennan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003068

Device Name: Savina

Intended Use:

Long-term ventilator for intensive care. For patient requiring tidal volume starting at 50 ml.

Sep. 2000

Dr. Gerd Holzapfel
R&D Intensive Care
Dräger Medizintechnik

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003068

(Optional Format 3-10-98)

Prescription Use Only